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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,858	03/02/2005	Hiroyoshi Hidaka	8279.829USWO	5428

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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08/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,858	Applicant(s) HIDAKA ET AL.
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. The response filed on **6/18/10** has been entered.
2. Applicant's arguments filed 6/18/10 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 15-16 and 27 are pending in this office action.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-16 and 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hidaka et al. (US Patent 5,972,976) in view of Goodman and Gilman (1996) as made of record in Paper No. 20091218 and as follows.

Applicant argues that “Claim 27 is directed to a method for treating a patient suffering from at least one malignant tumor selected from the group consisting of blood cancer, leukemia, human colon adenocarcinoma, gastrointestinal cancer, lung cancer, breast cancer, and prostate cancer. The method comprises administering a therapeutically effective amount of (E)-4-[2-[2-[N-acetyl-N-[(p-methoxyphenyl)sulfonyl]amino]phenyl]ethenyl]pyridine 1-oxide (referred to as HMN-214 hereinafter) or a pharmaceutically acceptable salt thereof in combination with cisplatin. Applicant further argues that claim 27 also recites that the therapeutically effective amount of (E)-4-[2-[2-[N-acetyl-N-[(p-methoxyphenyl)sulfonyl]amino]phenyl]pyridine 1-oxide with cisplatin gives a synergistic inhibitor/effect”. Applicant further argues that the “T/C value is an indicator that shows how long survival times of animals of a treated group are extended compare to those of a control group” and that the values reported reflects synergism.

In response careful consideration have been given to Applicant's argument and found not persuasive for several reasons:

1) the claims do not recite any dosage amount only an effective amount of (E)-4-[2-[2-[N-acetyl-N-[(p-methoxyphenyl)sulfonyl]amino]phenyl]pyridine 1-oxide administered simultaneously with cisplatin.

2) it is well known in the art that co administration of drugs give synergistic effect especially when the two drugs have different binding sites as taught by Goodman et al. (see page 1230 of Goodman and Gilman, para. 3).

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Examiner suggests deleting the term “effective amount” to a specific dosage amount that actually yields synergistic effect.

Summary of the rejection

Hidaka et al. teach a pharmaceutical composition for treating malignant tumor (see col. 1 lines 13+ such as colon cells, see col. 28, lines 40-45) with a compound of formula I wherein the compound is E) -4- [2- [2- [N-acetyl-N- [(p- methoxyphenyl)sulfonyl] amino] phenyl] ethenyl] pyridine 1 – oxide.

Although Hidaka fails to teach combinations with other known anticancer agents such as cisplatin, Goodman and Gilman teach that the antitumor agents cisplatin and carboplatin may be combined with other anticancer drugs for the treatment of cancers, such as breast, ovary and lung (see pages 1229 and 1230) wherein Goodman and Gilman specifically teach “drugs are generally more effective in combination and may be synergistic...”

Therefore one of ordinary skill in the art would have been motivated to combine a known anticancer drug employed in the treatment of breast cancer with the newly found drug of Hidaka that is capable of treating the same type of disease via a different mechanism because Goodman and Gilman teach the combination of anticancer drugs, which such may result in a synergistic effect. Accordingly, in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art.

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
7/15/10

/Michael Pak/
Primary Examiner, Art Unit 1646